SUMMARY OF SAFETY AND EFFECTIVENESS

Assigned 510(k) Number

OCT 2 8 2009

The assigned 510(k) number is K09 1984

Sponsor Name and Address

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA
90045-6900
(310) 645-8200

Contact

Clare Santulli
Sr.Regulatory Affairs Specialist
(914) 524-2701
(914) 524-3579 fax
clare.santulli@siemens.com

Device Name

Trade name:	IMMULITE® 2000 3gAllergy™ Specific IgE Assay
Classification:	Class II
Classification Names:	Radioallergosorbent (RAST) Immunological Test System
Regulation Number:	866.5750
Product Code:	DHB
Catalog Numbers:	L2KUN6 (600 tests)

Description of Device

IMMULITE® 2000 3gAllergy™ Specific IgE is a solid-phase, two-step, chemiluminescent immunoassay that exploits liquid phase kinetics in a bead format.[1,2] (U.S. Patent No. 4,778,751) It represents a significant advance over conventional methods relying on allergens attached to a solid-phase support, such as a paper disk.

The allergens are covalently bound to a soluble polymer/co-polymer matrix, which in turn is labeled with a ligand. The use of an amino acid co-polymer amplifies the amount of allergen that the matrix can support.

Incubation Cycles: 2 × 30 minutes.

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[1] El Shami AS, Alaba O. Liquid-phase *in vitro* allergen-specific IgE assay with *in situ* immobilization. Adv Biosci 1989;74:191–201.

[2] Alaba O, El Shami AS. Evaluation of non-specific IgE binding: comparison of two *in vitro* allergen assays. Adv Biosci 1989;74:203–14.

Indications for Use

For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Establishment Information

IMMULITE® 2000 3gAllergy Specific IgE assay is manufactured by Siemens Healthcare Diagnostics Inc. at the following locations:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
FDA Establishment #: 3005250747

Predicate

The purpose of this 510(k) submission is for clearance of twenty seven additional specific allergens, named in the table below, to be used with the IMMULITE® 2000 3gAllergy™ Specific IgE on the IMMULITE® 2000 analyzer.

1	F280–Black Pepper	14	F208 – Lemon
2	F260 – Broccoli	15	F182 – Lima Bean
3	F216 – Cabbage	16	F95 – Peach
4	F82 – Cheese-Mold Type	17	F94 – Pear
5	F242 – Cherry	18	F210 – Pineapple
6	F299 – Chestnut	19	F255 – Plum
7	F105 – Chocolate	20	F225 – Pumpkin
8	F221 – Coffee	21	F381 – Red Snapper
9	F244 – Cucumber	22	F337 – Sole
10	F259 – Grape	23	F214 – Spinach
11	F209 – Grapefruit	24	F54 – Sweet Potato
12	F42 – Haddock	25	F204 – Trout
13	F88 – Lamb	26	F284 – Turkey Meat
		27	F329 - Watermelon

FDA clearance was previously obtained for the assay kit and 196 specific allergens and allergen panels (K013134, K021206, K013135 and K021208).

Please note that the FDA clearances indicated above were in the name of Diagnostic Products Corporation which was acquired by Siemens Medical Solutions Diagnostics in July 2006. Siemens Medical Solutions Diagnostics was renamed Siemens Healthcare Diagnostics Inc. on January 1, 2008.

Precision

Precision studies were performed in accordance with Clinical Laboratory Standard Institute (CLSI) guidance: *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline-Second Edition.* CLSI document EP5-A2 (ISBN 1-56238-542-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004, assaying two aliquots of each test sample in two runs per day on 20 different days. Analysis of variance was used to estimate the within-run and total precision.

Three allergen lots were tested using three positive samples and one negative sample. Intra-assay and inter-assay precision for the positive samples were evaluated by calculating the kU/L dose percent coefficients of variation (%CV) for each positive sample. Non-specific binding (NSB) was monitored by testing the negative control sample.

Representative precision claims for each allergen tested are presented below:

Allergen Precision Claims*					
		Within-Run		Total	
Sample	Mean kU/L	SD kU/L	CV %	SD kU/L	CV %
Allergen = Black Pepper, Lot 115					
Positive #1	1.41	0.059	4.18	0.073	5.18
Positive #2	3.43	0.380	11.08	0.422	12.30
Positive #3	6.81	0.250	3.67	0.571	8.38
Allergen = Broccoli, Lot 114					
Positive #1	12.02	0.546	4.54	0.759	6.31
Positive #2	5.68	0.251	4.42	0.338	5.95
Positive #3	2.37	0.091	3.84	0.127	5.36
Allergen = Cabbage, Lot 117					
Positive #1	0.78	0.023	2.95	0.053	6.79
Positive #2	14.40	0.591	4.10	0.971	6.74
Positive #3	22.92	0.801	3.49	1.422	6.20
Allergen = Cheese, Mold Type, Lot 116					
Positive #1	1.20	0.037	3.08	0.059	4.92
Positive #2	1.66	0.052	3.13	0.067	4.04
Positive #3	6.04	0.241	3.99	0.287	4.75
Allergen = Cherry, Lot 118					
Positive #1	3.31	0.130	3.93	0.221	6.68
Positive #2	1.10	0.036	3.27	0.070	6.36
Positive #3	11.19	0.390	3.49	0.981	8.77
Allergen = Chestnut, Lot 114					
Positive #1	7.93	0.238	3.00	0.396	4.99
Positive #2	2.86	0.108	3.78	0.135	4.72
Positive #3	5.81	0.181	3.12	0.261	4.49
Allergen = Chocolate, Lot 118					
Positive #1	0.43	0.031	7.21	0.038	8.84
Positive #2	1.13	0.085	7.52	0.095	8.41
Positive #3	0.41	0.029	7.07	0.038	9.27
Allergen = Coffee, Lot 116					
Positive #1	0.58	0.020	3.45	0.041	7.07

Positive #2	1.84	0.075	4.08	0.128	6.96
Positive #3	0.61	0.024	3.93	0.048	7.87
Allergen = Cucumber, Lot 116					
Positive #1	2.85	0.097	3.40	0.167	5.86
Positive #2	2.10	0.082	3.90	0.168	8.00
Positive #3	8.38	0.256	3.05	0.621	7.41
Allergen = Grape, Lot 117					
Positive #1	5.21	0.189	3.63	0.292	5.60
Positive #2	1.29	0.047	3.64	0.064	4.96
Positive #3	14.20	0.464	3.27	0.707	4.98
Allergen = Grapefruit, Lot 116					
Positive #1	2.68	0.092	3.43	0.160	5.97
Positive #2	1.07	0.031	2.90	0.088	8.22
Positive #3	13.79	0.524	3.80	0.988	7.16
Allergen =Haddock, Lot 110					
Positive #1	0.84	0.031	3.69	0.038	4.52
Positive #2	5.21	0.176	3.38	0.268	5.14
Positive #3	8.66	0.387	4.47	0.413	4.77
Allergen = Lamb, Lot 115					
Positive #1	2.96	0.105	3.55	0.180	6.08
Positive #2	9.50	0.359	3.78	0.591	6.22
Positive #3	7.87	0.319	4.05	0.509	6.47
Allergen = Lemon, Lot 116					
Positive #1	12.13	0.407	3.36	0.621	5.12
Positive #2	1.16	0.048	4.14	0.065	5.60
Positive #3	3.88	0.147	3.79	0.266	6.86
Allergen =Lima Bean, Lot 111					
Positive #1	3.89	0.176	4.52	0.257	6.61
Positive #2	5.85	0.229	3.91	0.320	5.47
Positive #3	14.77	0.539	3.65	0.668	4.52
Allergen = Peach, Lot 119					
Positive #1	3.80	0.159	4.18	0.197	5.18
Positive #2	3.87	0.176	4.55	0.212	5.48
Positive #3	11.15	0.442	3.96	0.666	5.97
Allergen = Pear, Lot 116					

Positive #1	1.63	0.058	3.56	0.105	6.44
Positive #2	4.36	0.117	2.68	0.268	6.15
Positive #3	6.61	0.212	3.21	0.428	6.48
Allergen = Pineapple, Lot 115					
Positive #1	2.21	0.098	4.43	0.168	7.60
Positive #2	1.50	0.049	3.27	0.107	7.13
Positive #3	0.83	0.024	2.89	0.081	9.76
Allergen = Plum, Lot 113					
Positive #1	1.38	0.117	8.48	0.136	9.86
Positive #2	3.93	0.127	3.23	0.211	5.37
Positive #3	2.81	0.087	3.10	0.147	5.23
Allergen = Pumpkin, Lot 115					
Positive #1	0.98	0.063	6.43	0.076	7.76
Positive #2	3.33	0.136	4.08	0.187	5.62
Positive #3	8.92	0.306	3.43	0.413	4.63
Allergen = Red Snapper, Lot 110					
Positive #1	15.92	0.612	3.84	0.723	4.54
Positive #2	3.74	0.129	3.45	0.182	4.87
Positive #3	15.14	0.427	2.82	0.700	4.62
Allergen = Sole, Lot 110					
Positive #1	1.50	0.051	3.40	0.077	5.13
Positive #2	4.75	0.219	4.61	0.276	5.81
Positive #3	18.62	0.577	3.10	0.734	3.94
Allergen = Spinach, Lot 115					
Positive #1	0.91	0.027	2.97	0.039	4.29
Positive #2	1.73	0.054	3.12	0.085	4.91
Positive #3	14.80	0.405	2.74	0.685	4.63
Allergen = Sweet Potato Lot 113					
Positive #1	6.71	0.238	4.22	0.352	5.25
Positive #2	4.09	0.178	4.35	0.273	6.67
Positive #3	1.97	0.081	4.11	0.102	5.18
Allergen =Trout Lot 115					
Positive #1	30.71	0.945	3.08	1.825	5.94
Positive #2	1.72	0.058	3.37	0.097	5.64
Positive #3	17.28	0.646	3.74	0.926	5.36

Allergen = Turkey Meat, Lot 116					
Positive #1	1.36	0.045	3.31	0.117	8.60
Positive #2	4.80	0.15	3.25	0.211	4.40
Positive #3	6.99	0.233	3.33	0.642	9.18
Allergen = Watermelon, Lot 112					
Positive #1	1.62	0.064	3.95	0.122	7.53
Positive #2	5.03	0.172	3.42	0.345	6.86
Positive #3	19.25	0.561	2.91	1.250	6.49

* data are representative of one lot on one instrument

Linearity

For each allergen, two samples were diluted in 2-fold serial dilutions to 5 levels. The undiluted (neat) and diluted samples were tested with the specific allergen to demonstrate linearity at concentrations within the assay limits. Regression statistics for each allergen comparing observed to expected data are presented below.

Linearity

Allergen	Regression Equation	N	Slope	95% CI	Intercept	95% CI
Black Pepper	Y= 0.9975X +0.0404	12	0.9975	0.9761–1.0188	0.0404	–0.0165-0.0973
Broccoli	Y= 1.0035X +0.2560	12	1.0035	0.9666–1.0405	0.2560	–0.0089-0.5209
Cabbage	Y= 0.9976X+0.0231	12	0.9976	0.9883–1.0068	0.0231	–0.0077-0.0540
Cheese-Mold Type	Y= 0.9929X +0.0656	12	0.9929	0.9594–1.0264	0.0656	0.0110-0.1202
Cherry	Y= 1.0165X +0.2024	12	1.0165	0.9719–1.0612	0.2024	–0.1789-0.5838
Chestnut	Y= 10074X +0.2158	12	1.0074	0.9748–1.0399	0.2158	–0.0857-0.5173
Chocolate	Y= 1.0047X -0.0163	9	1.0047	0.9833–1.0261	–0.0163	–0.0349-0.0022
Coffee	Y= 0.9876X +0.0824	11	0.9876	0.9168–1.0584	0.0824	–0.0008-0.1655
Cucumber	Y=1.0003X +0.1336	12	1.0003	0.9756–1.0249	0.1336	–0.1292-0.3963
Grape	Y=1.0117X +0.1622	12	1.0117	0.9811–1.0423	0.1622	–0.1933-0.5177
Grapefruit	Y= 0.9967X +0.0264	12	0.9967	0.9816–1.0119	0.0264	–0.0277-0.0804
Haddock	Y= 1.0010X +0.0653	12	1.0010	0.9852–1.0169	0.0653	–0.1583-0.2888
Lamb	Y= 1.0233X -0.2153	12	1.0233	0.9966–1.0499	–0.2153	–0.4527-0.0221
Lemon	Y= 0.9995X +0.1424	12	0.9995	0.9836–1.0153	0.1424	0.0300-0.2549
Lima Bean	Y= 0.9973X +0.0791	12	0.9973	0.9778–1.0167	0.0791	0.0067-0.1514
Peach	Y= 0.9916X +0.1351	12	0.9916	0.9647–1.0185	0.1351	–0.2444-0.5145

Allergen	Regression Equation	N	Slope	95% CI	Intercept	95% CI
Pear	Y=1.0073X +0.4035	12	1.0073	0.9667–1.0480	0.4035	–0.1411-0.9481
Pineapple	Y= 0.9871X +0.0561	12	0.9871	0.9782–0.9960	0.0561	0.0373-0.0749
Plum	Y=1.0175X +0.0408	12	1.0175	0.9819–1.0531	0.0408	–0.2704-0.3521
Pumpkin	Y= 1.0033X +0.0589	12	1.0033	0.9805–1.0262	0.0589	–0.0278 -0.1455
Red Snapper	Y= 0.9914X + 0.0753	12	0.9914	0.9822–1.0006	0.0753	0.0421-0.1085
Sole	Y=0.9966X +0.0610	12	0.9966	0.9825–1.0106	0.0610	–0.0042-0.1262
Spinach	Y= 1.0046X + 0.1871	12	1.0046	0.9568–1.0523	0.1871	–0.0821-0.4563
Sweet Potato	Y= 0.9999X +0.1379	11	0.9999	0.9529–1.0469	0.1379	0.0074-0.2683
Trout	Y= 1.0038X -0.0478	12	1.0038	0.9896–1.0181	-0.0478	–0.2083-0.1127
Turkey Meat	Y= 1.0129X +0.1070	12	1.0129	0.9823–1.0436	0.1070	–0.0919-0.3058
Watermelon	Y= 1.0138X +0.0405	12	1.0138	0.9856–1.0420	0.0405	–0.2677-0.3486

Specificity (Inhibition) Studies

Specificity of each allergen was verified through competitive inhibition testing using a single serum sample or pool of sera. A negative sample was used to measure the background response.

To initiate the inhibition experiment, 70µL of undiluted and minimally 4 levels of 5-fold serially diluted inhibitor extract (at 5, 1, 0.2, 0.04 and 0.008 mg/mL) were mixed with 250µL of sample or pool. In some instances additional levels of inhibitor extract (at 0.0016, 0.00032, and 0.000064 mg/mL) were also used. This mixture was incubated at room temperature (15-28 °C) for 1 hour allowing the immunological reaction to occur. Each sample mixture containing the inhibitor extract and the appropriate controls was assayed with 1 lot of each allergen. The percent (%) inhibition was calculated according to the following formula:

$$\left[\frac{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})} - \text{sample response with inhibitor extract})}{(\text{Response of pos. control}_{(\text{pos. sample} - \text{neg. sample})})}\right] \times 100$$

The inhibition plots demonstrate that the allergens tested are inhibited by the relevant inhibitor extract in a concentration dependent fashion. Also, the target % inhibition of 50% for the highest inhibitor concentration tested was met. These results indicate specificity of Black Pepper, Broccoli, Cabbage, Cheese- Mold Type, Cherry, Chestnut, Chocolate, Coffee, Cucumber, Grape, Grapefruit, Haddock, Lamb, Lemon, Lima Bean, Peach, Pear, Pineapple, Plum, Pumpkin, Red Snapper, Sole, Spinach, Sweet Potato, Trout, Turkey Meat, and Watermelon allergens. Summary inhibition table is presented below.

Inhibitor Concentration (mg/mL)	% Inhibition	Inhibitor Concentration (mg/mL)	% Inhibition	Inhibitor Concentration (mg/mL)	% Inhibition
Black Pepper		**Broccoli**		**Cabbage**	
5	93.01	5	95.21	5	96.75
1	77.62	1	91.51	1	95.56
0.2	56.99	0.2	85.56	0.2	91.34
0.04	22.38	0.04	74.17	0.04	70.45
0.008	1.40	0.008	24.75	0.008	16.30
Cheese-Mold Type		**Cherry**		**Chestnut**	
5	89.34	5	98.94	5	95.98
1	88.83	1	92.40	1	90.12
0.2	80.71	0.2	76.56	0.2	49.64
0.04	74.11	0.04	57.76	0.04	0.00
0.008	16.75	0.008	46.57	0.008	2.70
Chocolate		**Coffee**		**Cucumber**	
5	79.53	5	74.53	5	97.89
1	82.46	1	66.98	1	96.22
0.2	50.29	0.2	39.62	0.2	91.22
0.04	27.49	0.04	13.21	0.04	84.76
0.008	5.26	0.008	10.85	0.008	35.31
				0.0016	9.35
Grape		**Grapefruit**		**Haddock** (inhibitor conc. starting at 0.2 mg/mL)	
5	85.56	5	97.78	0.2	97.33
1	52.22	1	93.13	0.04	90.80
0.2	23.33	0.2	82.32	0.008	83.47
0.04	26.67	0.04	15.76	0.0016	80.20
0.008	14.44	0.008	0.81	0.0032	70.73
				0.000064	18.47

Inhibitor Concentration (mg/mL)	% Inhibition		Inhibitor Concentration (mg/mL)	% Inhibition		Inhibitor Concentration (mg/mL)	% Inhibition
Lamb			**Lemon**			**Lima Bean**	
5	95.86		5	91.50		5	96.94
1	92.88		1	86.82		1	91.68
0.2	84.86		0.2	83.36		0.2	82.49
0.04	62.10		0.04	59.91		0.04	54.49
0.008	34.02		0.008	7.57		0.008	21.66
Peach			**Pear**			**Pineapple**	
5	97.28		5	85.31		5	88.36
1	92.41		1	71.19		1	83.60
0.2	83.46		0.2	57.06		0.2	72.49
0.04	74.25		0.04	49.72		0.04	42.86
0.008	45.01		0.008	27.68		0.008	20.11
Plum			**Pumpkin**			**Red Snapper** (inhibitor conc. starting at 0.2 mg/mL)	
5	97.86		5	93.18		0.2	83.58
1	82.91		1	83.36		0.04	74.68
0.2	67.67		0.2	57.98		0.008	76.29
0.04	46.50		0.04	33.97		0.0016	76.50
0.008	16.70		0.008	14.19		0.0032	46.46
						0.000064	5.79
Sole (inhibitor conc. starting at 1)			**Spinach**			**Sweet Potato**	
1	97.04		5	80.10		5	60.57
0.2	90.31		1	81.20		1	42.86
0.04	77.55		0.2	62.02		0.2	0.00
0.008	63.52		0.04	36.58		0.04	0.00
0.0016	47.50		0.008	15.75		0.008	3.43
0.0032	39.34						

Inhibitor Concentration (mg/mL)	% Inhibition		Inhibitor Concentration (mg/mL)	% Inhibition		Inhibitor Concentration (mg/mL)	% Inhibition
Trout			**Turket Meat**			**Watermelom**	
5	99.03		5	96.52		5	100.00
1	97.71		1	93.99		1	93.53
0.2	96.10		0.2	90.51		0.2	87.30
0.04	91.36		0.04	68.20		0.04	83.37
0.008	83.99		0.008	20.09		0.008	62.59
0.0016	78.25					0.0016	12.70
0.0032	60.21					0.0032	5.08
0.000064	12.99						

Clinical Performance Studies

Clinical performance was demonstrated by testing serum samples against specific allergens from clinically diagnosed atopic and non-atopic individuals. Allergen-specific testing was obtained using the IMMULITE® 2000 3gAllergy™ assay.

Data summary agreement of the IMMULITE® 2000 3gAllergy results to clinical data is presented in the table below.

IMMULITE® 2000	Clinical Data				
	Clinical	Normal	Total		
Positive	820	32	852		
Negative	418	2,848	3,266		
Total	1,238	2,880	4,118		
	66.2%	98.9%	89.1%		
	Sensitivity	Specificity	Agreement		
Lower Conf	**64%**	**99%**	**88%**		
Upper Conf	**69%**	**99%**	**90%**		

Allergens included: Black Pepper, Broccoli, Cabbage, Cheese Mold-Type, Cherry, Chestnut, Chocolate, Coffee, Cucumber, Grape, Grapefruit, Haddock, Lamb, Lemon, Lima Bean, Peach, Pear, Pineapple, Plum, Pumpkin, Red Snapper, Sole, Spinach, Sweet Potato, Trout, Turkey Meat, and Watermelon

IMMULITE® 2000 3gAllergy assay results for all allergens compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity.

Conclusions for all Studies

Allergens including Black Pepper, Broccoli, Cabbage, Cheese Mold-Type, Cherry, Chestnut, Chocolate, Coffee, Cucumber, Grape, Grapefruit, Haddock, Lamb, Lemon, Lima Bean, Peach, Pear, Pineapple, Plum, Pumpkin, Red Snapper, Sole, Spinach, Sweet Potato, Trout, Turkey Meat, and Watermelon for use with the IMMULITE® 2000 3gAllergy Specific IgE assay demonstrate acceptable analytical performance including precision, linearity and specificity. IMMULITE® 2000 assay results compare well with clinical documentation of presence or absence of signs, symptoms and other diagnostic evidence of allergen sensitivity. Substantial equivalence was demonstrated to clinical data, supporting the following intended use of the IMMULITE® 2000 3gAllergys Specific IgE assay and the twenty seven previously listed allergens:

> For *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics, Inc
c/o Ms. Clare Santulli
Senior RA/ QS Specialist
5210 Pacific Concourse Dr.
Los Angeles, CA 90045-6900

OCT 2 8 2009

Re: k091984
Trade/Device Name: IMMULITE® 2000 3gAllergy™ Specific IgE assay kit
Regulation Number: 21 CFR §866.5750
Regulation Name: Radioallergosorbent (RAST) immunological test system
Regulatory Class: Class II
Product Code: DHB
Dated: October 19, 2009
Received: October 23, 2009

Dear Ms. Clare Santulli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801);

medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091984

Device Name: IMMULITE 3gAllergy™ Specific IgE Assay

Indication For Use:

For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer — for the quantitative measurement of allergen-specific IgE in human serum, as an aid in the clinical diagnosis of IgE-mediated allergic disorders.

Prescription Use ___√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 091984